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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/763,987      | 01/21/2004  | Scott L. Childs      | 14245US02           | 9485             |

7590 09/13/2007  
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| EXAMINER |
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VALENROD, YEVGENY

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| ART UNIT | PAPER NUMBER |
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1621

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| MAIL DATE | DELIVERY MODE |
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09/13/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/763,987

Applicant(s)

CHILDS, SCOTT L.

Examiner

Yevgeny Valenrod

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-100 is/are pending in the application.
- 4a) Of the above claim(s) 1-57 and 61-99 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 58-60 and 100 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Rejections under 35 USC 112 1<sup>st</sup> and 35 USC 112 2<sup>nd</sup> paragraphs are withdrawn in view of applicants' remarks.

Rejection under 35 USC 102(b) made over Homeyer et al. is maintained.

Concerning Applicants' remarks:

In the first page of remarks Applicant has stated that claim 58 has been amended to more clearly indicate that the invention is directed to a method of screening for cocrystals. No such amendment is found in the claims filed on 7/9/07.

### ***New Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 58-60 and 100 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are directed to a method of screening for a cocrystal of a salt. However, the recited steps are directed to formation of the cocrystal. The claims do not encompass steps directed to a screening method. It is unclear what the nature of the invention is. Is it a screening method as the preamble suggests or is it a method of preparing a cocrystal as the limitations suggest?

Claims 58-60 and 100 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In lines 5-6 of claim 58 the limitation recites: "said crystal" it is unclear which crystal the limitation is referring to.

Claim 58 recites the limitation "said crystal" in lines 5-6. There is insufficient antecedent basis for this limitation in the claim.

***Maintained Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 58-60 rejected under 35 U.S.C. 102(b) as being anticipated by Homeyer et al. (US 2,665,277 ('277)).

The instant claims are directed to a method of forming a co-crystal. The steps involved are: a) Selecting a salt of an active agent, b) theorizing coordination, c) selecting a guest, d) preparing a solution, e) performing crystallization and f) forming a cocrystal.

Of the above steps, "theorizing coordination" is not given any patentable weight. The said step is purely mental with no physical consequences.

Homeyer et al. describe a method of making morphine phosphate hemihydrate. The said crystal contains a salt of an active agent (morphine phosphate) and a guest (water). The method (column 2 line 50 – column 3, line 7) described in '277 involves: selecting a salt of an active agent (morphine phosphate), selecting a guest (water), preparing a solution (morphine phosphate is mixed with water), performing crystallization (the mixture is cooled), forming a crystal (column 3, lines 6-7).

*Response to applicants' remarks*

Applicant has argued that the limitation "theorizing coordination of the counterion by hydrogen bond interaction within said crystal" was not considered in error. The Examiner maintains that "theorizing coordination" is not a patentable limitation. Although it is not a patentable limitation, Homeyer et al. inherently meet the said limitation. In order to prepare the cocrystal, Homeyer et al. had to consider the possible hydrogen bonding interactions, and how they would effect the cocrystal formation.

***Conclusion***

Claims 1-100 are pending

Claims 1-57 and 61-99 are withdrawn

Claims 58-60 and 100 are rejected

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yevgeny Valenrod whose telephone number is 571-272-9049. The examiner can normally be reached on 8:30am-5:00pm M-F.

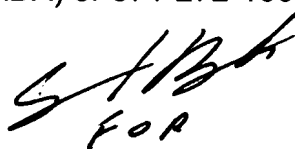
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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